

REMARKS

Claims 1 to 52 were pending and before the Examiner in the parent application. Claims 1, 15, 16, 17, 20, 23, 27, 28, 30, 38, 39 and 50 have been amended. Claims 32-37 have been cancelled. New claims 53 to 95 have been added. Furthermore, applicants have amended the disclosure to insert terms to refer to each of the nebulizer types specified in the disclosure: the nebulizers set forth in PCT Publication No. WO 91/14468 are designated "the Weston Nebulizer"; the nebulizers set forth in PCT Application No. WO 97/12687 are designated "the Jaeger Nebulizer A"; and the nebulizer portrayed in Fig. 6 of PCT Application No. WO 97/12687 is designated "the Jaeger Nebulizer B". Claims 38 and 81 therefore refer to the nebulizers set forth in PCT Publication No. WO 91/14468 and the nebulizer portrayed in Fig. 6 of PCT Application No. WO 97/12687, respectively. Applicants maintain that no new matter has been added thereby and therefore respectfully request that the Examiner enter and examine the new claims presented on the merits. Claims 1 to 95 are now pending and before the Examiner in this application.

In the parent application the Examiner rejected claims 38, 42, 44, 46, 48, 51, 81, 85, 87, 89, 91, and 94 under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In response, applicants have amended the claims and disclosure and traverse the Examiner's rejection insofar as it requires incorporation of the voluminous disclosure of these applications, as applicants do not believe they are essential material. As the Examiner may know, however, WO 97/20590 is the equivalent of U.S. Patent No. 6,453,795; WO 97/12687 is the equivalent of U.S. Patent No. 5,964,416; and WO 91/14468 is the equivalent of U.S. Patent No. 5,497,944. Accordingly, applicants would be willing to insert appropriate statements in the disclosure, for example, "U.S. Patent No. 5,497,944 (equivalent to WO 91/14468) is hereby incorporated by reference" in required places where PCT documents are incorporated by reference to satisfy the Examiner.

The Examiner rejected claims 1 to 37, 50, 53 to 80 and 93 under 35 U.S.C. § 102(b), as allegedly anticipated by Freund *et al.* (DE 19653969; U.S. Patent Application Publication No. US 2001/0008632 being used as a translation thereof).

In response, applicants respectfully traverse the Examiner's rejection. Freund *et al.* relates generally to aqueous medicament preparations. Although Freund *et al.* may mention many possible components for fabricating inhalation aerosols, Freund *et al.* does not provide any disclosure or guidance toward the specifically claimed combination of applicants' invention. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co.*, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987); *see also* M.P.E.P. § 2131. The ordinarily skilled artisan is not directed to the claimed invention including tiotropium. Accordingly, there is no anticipation of the claimed invention by Freund *et al.* and applicants respectfully request that the Examiner reconsider and withdraw this rejection.

The Examiner also rejected claims 1 to 37, 50, 53 to 80 and 93 under 35 U.S.C. § 102(b), as allegedly anticipated by Bozung *et al.* (DE 19921693; U.S. Patent No. 6,433,027 being used as a translation thereof).

Bozung. et al is directed at pharmaceutical compositions comprising combinations of Beta sympathomimetics and anticholinergics. In contrast, the claimed composition is directed at a composition comprising tiotropium as the active ingredient. Accordingly, the rejection under Section 102(e) should be reconsidered and withdrawn.

The Examiner also rejected claims 38 to 49, 51, 52, 81 to 92, 93, and 95 under 35 U.S.C. § 103(a), as allegedly unpatentable over Freund *et al.* and further in view of Weston *et al.* (WO 91/14468).

In response, applicants respectfully traverse the Examiner's rejection under 35 U.S.C. § 103(a) and maintain that the Examiner has failed to establish a *prima facie* case of obviousness against the instant invention. A *prima facie* case of obviousness requires the satisfaction of three criteria: (i) there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or combine reference teachings; (ii) there must be a reasonable expectation of success; and (iii) the references when combined must teach or suggest all of the claim limitations. M.P.E.P. § 2143.

Neither Freund *et al.* nor Weston *et al.*, alone or in combination, renders the special formulation of applicants claimed invention obvious, however, since neither reference, alone or in combination discloses, suggests, or even hints to one of skill in the art, much less with the required reasonable expectation of success, of the claimed combination of applicants' invention. As pointed out above, with respect to the anticipation rejection, Freund *et al.* does not provide any disclosure or embodiment of the combination of applicants' claimed invention. Since the Examiner is relying solely on Freund *et al.* to teach the formulation to be used in the nebulizer of Weston *et al.*, applicant maintains that Freund *et al.* is deficient in teaching the formulation used in applicants' claimed invention. The Examiner has the burden of showing a *prima facie* case of obviousness. *In re Bell*, 26 U.S.P.Q.2d 1529, 1530 (Fed. Cir. 1993); *In re Oetiker*, 24 U.S.P.Q.2d 1443, 1444 (Fed. Cir. 1992). The fact that Freund *et al.* nor Weston *et al.* contain elements of applicants' claimed invention alone does not render the claimed invention obvious. Rejecting claims solely by finding prior art corollaries for the claimed elements would permit an Examiner to use the claimed invention itself as a blueprint for piecing together elements in the prior art to defeat the patentability of the claimed invention, which is an illogical and inappropriate process by which to determine patentability. *Sensonics, Inc. v. Aerasonic Corp.*, 38 U.S.P.Q.2d 1551, 1554 (Fed. Cir. 1996); *In re Rouffet*, 47 U.S.P.Q.2d 1453 (Fed. Cir. 1998). Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching or suggestion or incentive to do so. *ACS Hosp. Sys., Inc. v. Montefiore Hosp.*, 221 U.S.P.Q. 929, 933 (Fed. Cir. 1984). Virtually all inventions are combinations of old elements. *Environmental Designs, Ltd. v. Union Oil Co.*, 218 U.S.P.Q. 865, 870 (Fed. Cir. 1983). Thus, the mere mention of elements of applicants' claimed invention in these references does not alone render obvious their particular combination. As applicants maintain that the Examiner has failed to establish a *prima facie* case of obviousness against the instant invention, applicants respectfully request that the Examiner reconsider and withdraw this rejection.

Applicants maintain that the above remarks and amendments overcome the Examiner's rejection or render the Examiner's rejections moot. Applicants therefore submit that all the pending claims are allowable and respectfully solicit a Notice of Allowance for all of the pending claims. If the Examiner feels that a telephone interview would be helpful in

advancing prosecution of this application, the Examiner is invited to contact the attorney below.

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Respectfully submitted,



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